

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :
Jay N. COHN et al. :
Serial No. Unknown : Group Art Unit:
Filed: Herewith : Examiner:
For: KITS OF HYDRALAZINE COMPOUNDS AND ISOSORBIDE DINITRATE
AND/OR ISOSORBIDE MONONITRATE

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached form PTO-1449. It is respectfully requested that the documents be expressly considered during the prosecution of this application, and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom. Copies of any cited U.S. Patents and U.S. Patent Publications are not being submitted in accordance with 37 CFR 1.98(a)(2)(i).

This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required.

In accordance with 37 C.F.R. § 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search had been made or that information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item, and Applicant reserves the right to prove that the date of publication is in fact different.

Application No.: Unassigned
Filed: Herewith
Atty. Docket No. 102258.288US3

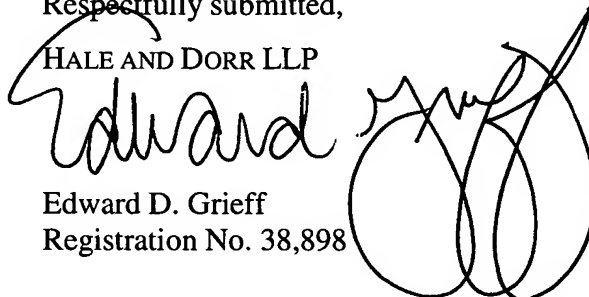
The references listed on Sheets 1 -7 of Form PTO-1449 were cited by or submitted to the U.S. Patent and Trademark Office in parent application Serial No. 09/658,261, filed September 8, 2000 and parent application Serial No. 10/210,113, filed August 2, 2002, which is relied upon for an earlier filing date under 35 USC § 120. Copies of these references are not attached under 37 CFR 1.98(d).

No fee is believed to be required, however, the Commissioner is authorized to charge any deficiency in any fees pursuant to 37 CFR § 1.17 associated with this communication and to credit any excess payment to Deposit Account No. 08-0219.

Respectfully submitted,

HALE AND DORR LLP

Edward D. Grief
Registration No. 38,898

A handwritten signature in black ink, appearing to read "Edward D. Grief", is written over the printed name and registration number. The signature is stylized and fluid.

1455 Pennsylvania Avenue, NW
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TEL 202.942.8400 EDG/mgm
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Date:

April 15, 2004

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Application Number:

Filing Date

First Named Inventor

Art Unit

Examiner Name

Attorney Docket Number

Sheet 1

Of

7.5

102258-286

U. S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		WO 02/34303 A1	05-02-2002	Loscalzo et al		
		WO 01/35961 A1	05-25-2001	Loscalzo et al		

Examiner Signature	Date Considered
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	
			Filing Date	
			First Named Inventor	Cohn
			Group Art Unit	
			Examiner Name	
			Attorney Docket Number	102258.288
Sheet	2	of	7	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Johnson, Clinical Pharmacy, Vol. 5, pages 536 and 541 (1986).	
		Massie et al, Br. Heart J., 45:376-384 (1981).	
		Turner et al, The American Journal of Cardiology, 47:910-916 (1981).	
		Massie et al, Circulation, 63(3):658-664 (1981).	
		Nelson et al, Journal of Cardiovascular Pharmacology, 5(4):574-579 (1983).	
		Leier et al, Circulation, 63(1):102-109 (1981).	
		Wilson et al, The American Journal of Medicine, 71:627-633 (1981).	
		Biddle et al, J. Clin. Pharmacol., 21:343-350 (1981).	
		Magorien et al, Clinical Research, 27(4):A617 (1979).	
		Turner et al, Clinical Research, 29(2):246A (1981).	
		Hibiya et al, Japanese Circulation Journal, 45:966 (Abstract No. 338) (1981).	

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		Application Number	102258.288
		Filing Date	1990.07.20
		First Named Inventor	Cohn
		Group Art Unit	
		Examiner Name	
Sheet 3 of 7	Attorney Docket Number	102258.288 U.S.	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Franciosa et al, Circulation, 59(6):1085-1091 (1979).	
		Lanas et al, Rev. Med. Chile, 107:926-930 (1979).	
		Usdin et al, Coeur, 10(1):119-128 (1979).	
		Burnier et al, Hypertension, 22(3):339-347 (1993).	
		von Lutterotti et al, American Journal of Hypertension, 4(4 Part 2):346S-349S (1991).	

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				Application Number	
				Filing Date	
				First Named Inventor	Cohn
				Group Art Unit	
				Examiner Name	
Sheet	4	of	7	Attorney Docket Number	102258.288

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				Application Number			
				Filing Date		1 30 7 2002	
				First Named Inventor		Cohn	
				Group Art Unit			
Examiner Name							
Sheet	5	of	7	Attorney Docket Number	102258.288		

[illegible][illegible]Date
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Sheet 6 of 7

Complete If Known

Application Number	
Filing Date	
First Named Inventor	Cohn
Group Art Unit	
Examiner Name	
Attorney Docket Number	102258.288

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS


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		Cohn et al, The New England Journal of Medicine, 325(5):303-310 (1991).	
		Cohn et al, The New England Journal of Medicine, 314(24):1547-1552 (1986).	
		Carson et al, Circulation, Supplement I, 92(8):I31-I32, Abstract No. 0145 (1995).	
		Francis et al, Circulation, Supplement VI, 87(6):VI40-VI48 (1993).	
		Pierpont et al, Chest, 73(1):8-13 (1978).	
		Massie et al, The American Journal of Cardiology, 40:794-801 (1977).	
		Kaplan et al, Annals of Internal Medicine, 84:639-645 (1976).	
		Bauer et al, Circulation, 84(1):35-39 (1991).	
		The SOLVD Investigators, The New England Journal of Medicine, 327(10):685-691 (1992).	
		Ziesche et al, Circulation, 87(6):VI56-VI64 (1993).	
		Rector et al, Circulation, 87(6):VI71-VI77 (1993).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number		
			Filing Date	2	
			First Named Inventor		
			Group Art Unit		
			Examiner Name		
Sheet	7	of	7	Attorney Docket Number	102258.288

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
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		Carson et al, Journal of Cardiac Failure, 5(3):178-187 (September 10, 1999).	
		Dries et al, The New England Journal of Medicine, 340(8):609-616 (February 25, 1999).	
		Freedman et al, Drugs, 54 (Supplement 3):41-50 (1997).	
		Sherman et al, Cardiologia, 42(2):177-187 (1997).	
		Biegelson et al, Coronary Artery Disease, 10:241-256 (1999).	
		Rudd et al, Am. J. Physiol., 277(46):H732-H739 (1999).	
		Hammerman et al, Am. J. Physiol., 277(46):H1579-1592 (1999).	
		Loscalzo et al, Transactions of the American and Climatological Ass., 111:158-163 (2000).	
		Dupuis, Cardiovascular Drugs and Therapy, 8(3):501-507 (1994).	

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